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In the Supreme Court of the United States

OCTOBER TERM, 1966.

No. 336

THE TOILET GOODS ASSOCIATION, INC., ET AL.,
PETITIONERS

v.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER
OF FOOD AND DRUGS

No. 438

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION,
AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER
OF FOOD AND DRUGS, PETITIONERS

v.

THE TOILET GOODS ASSOCIATION, ET AL.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF
APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR RESPONDENTS IN NO. 336 AND FOR PETITIONERS
IN NO. 438

OPINIONS BELOW

The opinion of the court of appeals (R. 119-138) is reported at 360 F. 2d 677. The first opinion of the district court (R. 67-76) is reported at 235 F. Supp. 648; the second (R. 48-53) is not reported.

JURISDICTION

The judgment of the court of appeals was entered on April 13, 1966 (R. 138-139). The petition for a writ of certiorari in No. 336 was filed on July 12, 1966. On July 7, 1966, Mr. Justice Stewart extended the time for filing a petition in No. 438 to and including August 11, 1966 (R. 140), and the petition was filed on that date. Both petitions were granted on October 10, 1966 (R. 141, 142). The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether certain interpretive regulations issued by the Commissioner of Food and Drugs for the enforcement of the 1960 "Color Additive" Amendments to the Federal Food, Drug and Cosmetic Act may be challenged prior to their enforcement in an action seeking declaratory and injunctive relief.

STATUTES AND REGULATIONS INVOLVED

The relevant statute and regulations are set forth in the Appendix, *infra*, pp. 23-38.

STATEMENT

In 1960 Congress enacted the Color Additive Amendments (74 Stat. 397, 21 U.S.C. 321) to the Federal Food, Drug and Cosmetic Act of 1938. Insofar as pertinent here, these amendments provide that a cosmetic shall be deemed adulterated if it is, or it bears or contains a "color additive" that has not been listed and certified as safe for its intended use under regulations to be issued by the Secretary (except where the additive has been administratively exempted from such certification requirements) (Sec-

tions 706 (a), (f), pp. 29, 34, *infra*). The amendments detail the pre-marketing standards the Food and Drug Administration is to apply in determining whether color additives will be safe for use (Sec. 706(b), p. 31, *infra*), and provide that administrative regulations should issue to specify the conditions of safe use, including any needed tolerances or other restrictions applicable to assure safety in use (Sections 706(b)(3), 706(c), pp. 29, 32, *infra*).

Section 201(t)(1) of the Food, Drug and Cosmetic Act, as amended in 1960, defines a "color additive" as:

(A) * * * a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto * * *.

On June 22, 1963, the Commissioner of Food and Drugs under delegated authority from the Secretary promulgated interpretive and procedural regulations for the administration of the Color Additive Amendments (28 Fed. Reg. 6439, 21 C.F.R. 8.1 *et seq.*; see pp. 34-35, *infra*).¹ Four of those regulations are

¹ About a year and a half earlier, on January 24, 1961, the Commissioner of Food and Drugs had given public notice of his intent to adopt such regulations and had offered an opportunity for all interested persons to present their views in writing (26 Fed. Reg. 679). Numerous comments, including some from the plaintiffs in this suit, were submitted and evaluated before the regulations were issued.

challenged in this lawsuit. Two (21 C.F.R. 8.1(f), and (m)) interpreted the statutory definition of "color additive" to include: (1) all finished cosmetic products intended for coloring the human body (*i.e.*, lipstick, rouge, eye makeup colors and related cosmetics) and (2) all "diluents"—non-pigmented materials with which colors are mixed to facilitate their use in food, drugs, cosmetics and for coloring the human body. The third (21 C.F.R. 8.1(u)) provided that "hair dyes", the injurious qualities of which could not be ascertained by the patch test required by Section 601(a) of the Act, were not within the "hair dye" exemption granted by the statute. The fourth provided that the Food and Drug Commissioner "may immediately suspend certification service" when the manufacturer has "[r]efused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived" (21 C.F.R. 8.28(2)(4)).²

In November 1963, respondents filed a complaint in the United States District Court for the Southern

² Subsection (b) of 21 C.F.R. 8.28—the validity of which is not challenged—provides that "[u]pon receipt of the notice of suspension of service, the person so notified may request a hearing upon the factual basis for the suspension." See 21 C.F.R. 130.14–130.26, 130.31.

³ For the sake of clarity the respondents in No. 438 (who are also the petitioners in No. 336) are hereinafter referred to as "respondents", and the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs are throughout referred to as the "petitioners". The Toilet Goods Associa-

District of New York under the Declaratory Judgments Act and the Administrative Procedure Act seeking injunctive relief and a declaration that the four regulations constituted an unauthorized interpretation of the statutory amendments (R. 1-43). The complaint alleged that Congress had not intended in the Color Additive Amendments to subject all finished cosmetic products, all diluents and certain hair dyes to the pre-marketing listing and certification requirements of the statute and that it did not contemplate that the factory inspection provisions of the Act (Section 704, 21 U.S.C. 374, p. 34, *infra*) would extend to the formulae and manufacturing processes for cosmetics. The complaint also alleged that the regulations threatened immediate and irreparable injury to respondents in that they either had to meet the requirements of listing, testing and certification or exemption from certification at great financial

tion is a trade association of cosmetic manufacturers whose members are said to produce in excess of 90% of the annual sales of cosmetics in the United States. The forty other respondents are manufacturers ~~and~~ and distributors of cosmetic products.

Throughout this litigation there has been a dispute between the parties as to the coverage of the finished cosmetic product and diluent regulations. Respondents have claimed throughout that the regulations in effect, establish a pre-marketing licensing system for *all* cosmetic products and ingredients. It is the view of the Food and Drug Administration that the regulations have a more limited scope, applying in terms only to those cosmetics that impart color to the human body and only to those diluents which actually function to facilitate the use of the pure color materials in the product in which such materials are used. As for cosmetics which do not impart color to the human body (such as perfume), the Food and Drug Administration does not require pre-marketing licensing, but only proof of safety of the color ingredients for their intended use.

expense, disruption of long-settled business practices, curtailment of new product distribution, and disclosure of secret formulae and processes, or else face civil or criminal suits for noncompliance. It was alleged that the institution of such proceedings would seriously injure consumer confidence in respondent's products (R. 21-26; 29-31; 37-38; 41).

Petitioners moved to dismiss (R. 53-67) asserting, *inter alia*, that the regulations were consistent with the Congressional purpose of insuring consumer safety in the use of color additives and that judicial review at this juncture was inappropriate and not authorized by any statute, including the Declaratory Judgments Act.

The district court denied the motion to dismiss, finding that the complaint did set forth a controversy as to each of the challenged regulations (R. 67-76.) The court also denied respondents' motion for summary judgment, however, and set the case for trial. Although the questions presented involved, in the court's view, essentially matters of statutory interpretation, expert testimony was believed helpful on "the technical problems involved" (R. 75). The court also stated that "since professionally qualified representatives of both plaintiffs and defendants were present during the hearings and debates which preceded the passage of the 1960 Color Additive Amendments it would be helpful to hear their testimony relative to legislative intent, which, presumably, they had an important role in shaping and assisting" (*ibid.*).

About a year later (after pre-trial discovery proceedings), the district court permitted petitioners to renew their motions to dismiss and for summary judg-

ment (R. 76-77). These motions requested the court to reconsider its ruling on the issue of justiciability, *inter alia*, in light of the Third Circuit's decision in *Abbott Laboratories v. Celebrezze*, 352 F. 2d 286, reversing, *per curiam*, 228 F. Supp. 855 (D. Del.), which held that the validity of administrative regulations interpreting certain provisions of the 1962 Drug Amendments to the Federal Food, Drug and Cosmetic Act were not subject to review by way of declaratory judgment in advance of a specific enforcement case (R. 76-80). The district court in this case adhered to its prior ruling, but it certified an interlocutory appeal under 28 U.S.C. 1292(b) to the Court of Appeals for the Second Circuit (R. 46-53).

The court of appeals affirmed in part and reversed in part (R. 119-139).⁵ With respect to the three regulations interpreting the statute as requiring that color-imparting cosmetics, diluents and certain hair dye be subject to pre-marketing listing and certification, the court held the question of their validity ripe for judicial resolution (R. 136-137). In so ruling, the court expressly rejected the Third Circuit's conclusion in *Abbott Laboratories* that the judicial review procedures specifically provided by the Food, Drug and Cosmetic Act were meant to be exclusive procedures to obtain pre-enforcement review (R. 135-136). With respect to the regulation relating to inspection of formulae and processes, the court found judicial review premature at this stage since that regulation was cast in permissive terms, no action had

⁵ While the instant case was *sub judice* in the court of appeals, this Court granted certiorari in *Abbott Laboratories v. Gardner*, 383 U.S. 924, No. 39, this Term.

been taken or threatened thereunder, it appeared that adequate relief by way of a hearing and judicial review were authorized by other regulations if the provision were in fact invoked, and protection of the public interest required that review of this regulation "be on a case by case basis and with a factual record * * *" (R. 137-138).

INTRODUCTION AND SUMMARY

The instant case, on its face, raises issues of justiciability closely akin to those discussed in some detail on our brief in *Abbott Laboratories v. Gardner*, No. 39, this Term. We believe that the regulations being challenged here, like those at issue in *Abbott Laboratories*, are not of the kind which the Congresses enacting the Food, Drug and Cosmetic Act of 1938 and Color Additive Amendments of 1960 intended to leave open to pre-enforcement judicial review. In the present case, as in *Abbott Laboratories*, "interpretive" regulations are involved, and they merely announce, in advance of enforcement, certain categories of products to which the Food and Drug Administration believes the Color Additives Amendments applicable. And here, as in *Abbott Laboratories*, we believe that an evaluation of "ripeness" factors warrants the conclusion that, entirely apart from the Food, Drug and Cosmetic Act itself, it would be premature for the courts to pass, at this juncture, on the claims made by respondents.

Before briefly elaborating these two points, we think it essential, however, to point out what this case does not involve. Variants in expression in re-

spondents' complaint and certain discussion in their brief in the court of appeals appear to draw into this litigation a challenge to a much more fundamental exercise of authority by the Food and Drug Administration which, we submit, is not presented by the complaint and by the narrow issues actually before the district court.

The Color Additive Amendments of 1960 were enacted, in part, to modify the former color provisions as they had been construed by this Court in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153. In the *Florida Citrus* case this Court, at the government's urging, had read the 1938 provisions (which applied only to coal-tar colors) as empowering the Food and Drug Administration to list and certify as permissible for use in foods, drugs and cosmetics only such coal-tar colors as are "harmless"; it rejected the claim that the 1938 Act imposed on the Administrator the duty, or gave him the authority, to determine whether each coal-tar color was harmful as used—*i.e.*, "taken in a particular way and in particular quantities" (358 U.S. at 163). The 1938 Act, in other words, was read as requiring that the coal-tar colors, in and of themselves, be examined, and that, if harmless, they be listed and certified for unrestricted use. The effect of the Act was to prohibit any use whatever of colors which exhibited poisonous properties in doses larger than those which might actually be used. Industry representatives, who had been urging amendments to the color provisions for some time,

thereafter pressed the Congress to adopt a "safety-in-use" test which would permit the use of color additives wherever, in the context of their particular use, they could be shown to be harmless.

To meet the criticisms of the color industry while retaining comprehensive consumer protection, the Secretary recommended to Congress the substantial overhaul of the color provisions which ultimately took the form of the Color Additive Amendments of 1960. That statute applied safety pre-clearance conditions to all natural and synthetic colors (not just coal-tar colors) and directed a re-evaluation of the safety of all colors, including those which had been in use for a long time. In addition, and what is particularly relevant here, the statute broadly delegated to the Commissioner the authority either to list and clear a color for unrestricted use or to permit "more limited use or uses * * * for which it is suitable and may safely be employed", and to "prescribe the conditions under which [it] may be safely employed for such use or uses * * *." Section 706(b), 21 U.S.C. 376(b), p. 30, *infra*. In determining whether and how to permit use for limited purposes of a color which could not be deemed "harmless" the Commissioner was directed to consider at least four factors specifically enumerated in Section 706(b)(5) (p. 31, *infra*), among which are the probable consumption of, or exposure from, the color additive and of any substance formed in foods, drugs or cosmetics on account of its use.

It is entirely clear from the legislative history of 1960 amendments^{*} and from the plain statutory terms that Congress intended to vest in the Commissioner the powers necessary to administer a "safety-in-use" standard for color additives. In adopting a standard which imposed on the Commissioner the burden described by this Court in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 162, of "examination of the effect of the use of colors in the context of" foods, drugs and cosmetics, Congress was surely not disabling the Commissioner from taking the necessary steps to determine whether color additives, *as used in a particular product*, will be safe for their intended use.

The issue which somewhat clouds this case involves the exercise of that necessary power. Finished cosmetic products which impart color to the human body—the subject of one of the challenged regulations in this case—are, beyond any doubt, products which may and often must be examined by the Commissioner to determine, at the very least, how the coloring ingredient contained therein is being used and whether, as used, it will be safe when applied to the lips or on other parts of the human body. Similarly, diluents must often be examined in order to determine whether and to what extent they react with color components. We do not view this case as raising any question of the Commissioner's power to demand that such finished products or diluents be submitted and tested in order to determine whether

* See S. Rep. No. 795, 86th Cong., 1st Sess. (1959); H. Rep. No. 1761, 86th Cong., 2d Sess. (1960).

and under what conditions their coloring ingredient is to be certified and listed as permissible for use. The challenged interpretation of the statute prohibits the sale of any finished color-imparting cosmetic product if that finished product is not itself listed as safe and certified or exempted. We stress this point only to emphasize that the Commissioner's power to require the submission and testing of finished products containing color additives or, indeed, of any other ingredient in a finished product of which a color is a component, does not depend upon whether the regulations here being challenged are valid. The authority to impose these requirements is merely a necessary adjunct of the duty to determine "safety-in-use," and regulations governing such submissions are, therefore, plainly within the scope of Section 701(a)'s authorization to promulgate regulations "for the efficient enforcement" of the Act.

1. Here, as in *Abbott Laboratories*, No. 39, this Term, review at this juncture was impliedly banned by the specific review provisions of the 1938 Act and the 1960 Amendments. The challenged regulations merely interpret provisions of the Act, and Congress did not intend such interpretations to be reviewable prior to their enforcement. Nor does the fact that the agency chose to proceed by formal rule-making under Section 4 of the Administrative Procedure Act subject the interpretive regulations to review at this juncture.

2. Apart from the specific review provisions of the Food, Drug and Cosmetic Act, the controversy is not "ripe" for review because respondents are not pres-

ently subjected to any serious harm as a result of the issuance of the regulations. The Food and Drug Administration plainly has the authority to examine diluents and finished cosmetic products to determine whether their color ingredients are safe for use. Consequently, respondents will not be injured by the regulations until their color ingredients are approved for use and they then attempt to sell them without separate listing or certification.

3. The court below was plainly right in concluding that the challenge to the factory inspection regulation was totally premature. Respondents have adequate remedies to challenge any consequences flowing from failure to allow inspection, if inspection is ever attempted.

ARGUMENT

I

THE CONGRESSES WHICH ENACTED THE FOOD, DRUG AND COSMETIC ACT AND THE COLOR ADDITIVE AMENDMENTS INTENDED TO BAR PRE-ENFORCEMENT JUDICIAL REVIEW OF REGULATIONS SUCH AS THOSE INVOLVED IN THIS CASE

As we have demonstrated in our brief in *Abbott Laboratories*, No. 39, this Term pp. 11-35, Congress, in the review provisions of the Food, Drug, and Cosmetic Act of 1938, struck a compromise. To overcome industry opposition based on a fear of potential administrative usurpation of power in the issuance of regulations having the force and effect of a statute, Congress authorized direct review of such "legislative" regulations in courts of appeals after their adoption but before they became effective (Section

701(f)(1), p. 27, *infra*). On the other hand, to prevent any delay in the enforcement of the remedial provisions of the Act, as they were construed by the administrative agency through the issuance of interpretive regulations, Congress intended to defer review of such interpretations until the regulation had been applied in a specific case. This "highly selective" pattern of review—marked by Congress' specific enumeration of instances when it wished pre-enforcement judicial review and its silence when it did not—was relied on by this Court in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 600–601, which held that the basis for seizures under the Act was not reviewable in advance of an enforcement case.

The Color Additive Amendments of 1960 (adopted by Congress with the gloss of *Mytinger*) manifest a continued adherence by Congress, twenty-two years after the adoption of the 1938 Act, to the original legislative design. The 1960 provisions amended Section 706 to provide that a color additive may not be used unless it receives pre-marketing clearance under regulations to be issued by the Food and Drug Administration pursuant to detailed statutory standards of "safety-in-use" (Section 706(b)). The Food and Drug Administration is directed to list color additives under the conditions under which they may safely be used and to certify batches of additives listed as safe (Sections 706(a)(1), (c), pp. 29, 32, *infra*). No such regulations for cosmetics or cosmetic colors have yet been promulgated, but, when they are, they will plainly be "legislative" in character. They will result from a delegation of power to the administrative agency to

fill the particulars of the statutory scheme which Congress wished implemented. Congress specifically provided for their judicial review before they are to become effective (see Section 706(d), pp. 32-33, *infra*).

The regulations challenged here are different in character. The finished cosmetic, diluent and hair dye regulations are simply administrative interpretations of the Congressional mandate. And it is that legislative direction, not the administrative interpretation, which makes the affirmative demands on the cosmetic industry. In every significant sense, the Food and Drug Administration's construction of the statutory term "color additive" and of the statutory hair-dye exemption is like the National Labor Relations Board's construction of the statutory term "employee," which this Court reviewed in a specific enforcement case in *National Labor Relations Board v. Hearst Publications, Inc.*, 322 U.S. 111. The Food and Drug Administration is authorized to act by rule-making, not adjudication. Hence it cannot announce its understanding of statutory standards, as, for example, can the National Labor Relations Board (see, e.g., *Brooks v. National Labor Relations Board*, 348 U.S. 96; *National Labor Relations Board v. Insurance Agents*, 361 U.S. 477) or the Federal Trade Commission (see, e.g., *Federal Trade Commission v. Mary Carter Paint Co.*, 382 U.S. 46, and authorities cited *id.* at 47, n. 3) in the context of particular cases. Its only alternatives are to proceed informally—a course under which it would not have the benefit of the views of the affected industry or any other form of external detailed scrutiny of its proposed

interpretation--or to issue the statutory interpretation as part of a rule-making proceeding in which interested parties would have an opportunity to present their views. The fact that the agency chose to proceed under Section 4 of the Administrative Procedure Act in this fashion should not subject its interpretation to a challenge which would otherwise be premature under the scheme contemplated by Congress for the enforcement of the Food, Drug and Cosmetic Act. As we have said, review will follow the issuance of specific color additive regulations or when an enforcement case is initiated.

II

THE REGULATIONS ARE NOT RIPE FOR JUDICIAL REVIEW

Here, as in our brief in *Abbott Laboratories*, No. 39, this Term, pp. 35-55, we contend alternatively that the controversy between respondents and the Food and Drug Administration has not yet achieved the degree of certainty and particularity required to make it "ripe" for judicial decision under the Declaratory Judgments Act.

There is little substance to respondents' assertion that awaiting an enforcement proceeding or following the administrative procedure specifically authorized under the statute would harm them in an immediate and serious fashion. What must be emphasized in this regard is that the critical issue, on this phase of the case, is not whether the regulations, if they are ultimately sustained, require some change in respondents' manner of doing business, but whether the effect on respondents is likely to be serious or ir-

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reparable if they are compelled to resort to remedies ~~when~~ ^{other than those} specifically enumerated.

The heart of respondents' claim with respect to the finished cosmetic, diluent and hair-dye regulations is that Congress did not intend to require that they be cleared and listed before being sold or used in any product being sold.¹ It is plain, however, that except to the extent that provisional listings now permit their sale without certification, the color additive components of these products must be tested, listed and certified as permissible for their intended use prior to any sale of the finished product. On its face, therefore, it is quite apparent that respondents' injury is distant and speculative, for even if color-imparting cosmetics are, as they contend, not "color additives" within the meaning of the statute, no present obligation is imposed upon them. Only when and if the coloring components of the cosmetics are approved, listed and certified for use in those cosmetics or for use with specified diluents will respondents be confronted with practical consequences arising out of the difference of view between themselves and the Food and Drug Administration.

At that juncture the question will be whether respondents must also obtain separate listing and certification or exemption therefrom for their particular finished color-imparting cosmetics before these products may be offered for sale. No substantial injury will be suffered at that stage, we submit, if respondents apply, pursuant to Section 706(b)(2)(A), to have their approved colors and their diluents listed.

¹ We emphasize again (see pp. 8-12, *supra*) that this cannot be read as a challenge to the Secretary's power to examine these products as part of a safety-in-use determination.

in their finished cosmetics on the ground that the color additive ingredients have already been approved for the particular use to which they are put or for combination with the diluents with which they are combined. If, under the interpretation of the statute incorporated in the challenged regulations, the Food and Drug Administration refuses to consider the prior safety-in-use determination as conclusive and requires an independent examination of the finished product, the issue of statutory construction will be squarely presented, in a concrete case, to a court of appeals under the judicial review procedures of Section 706(d), which incorporates Section 701(e), (f), and (g).

Nor, we submit, would there be any real hardship if, in these circumstances, respondents chose to await a condemnation suit. A proceeding in which the issue would be whether separate listing and certification is required for a color-imparting cosmetic whose color ingredient has been approved, listed and certified for that particular use would be a far more appropriate and concrete way of determining the question which separates respondents and the Food and Drug Administration than the means chosen here.

• A condemnation proceeding of the kind described above would be more suitable not merely because it would deal with the controversy at the point in time where it made a practical difference and because it would involve no serious hardship to respondents,⁸

⁸ We do not believe that there is substance to the claim that the seizure authorized by the statute would seriously affect the reputation of the company whose product was seized since it would be quite clear to the public what the basis for the seizure is. And we reaffirm here what we said in our brief in *Abbott*

but also because limiting the remedy in that way would prevent the multiplicity of suits which might otherwise occur. The complaint in this case shows, for example, that the plaintiff corporations reside, for venue purposes under 28 U.S.C. 1391(e)(4), in thirteen different States. If the present action were

Laboratories, No. 39, this Term, p. 41; that where a *bona fide* close question of statutory construction is involved, it is not the policy of the Food and Drug Administration or the Department of Justice to determine that issue in a lawsuit involving severe penalties such as criminal proceedings or multiple seizures.

The alleged excessive cost of separately listing and certifying finished cosmetic products, diluents and the assertedly exempt hair dyes (R. 99-102) is a consideration going to the merits—*i.e.*, to whether the administrative construction of the Act is correct—and not to the issues of ripeness since those costs need not be incurred, in any event, until after the issue is resolved. We also note that the \$2,600 filing charge is not a fee but a deposit to cover processing costs, so that any excess may be returned. 21 C.F.R. 8.50(c). Moreover, there is no requirement that each shade or ingredient of a cosmetic or each diluent be listed separately; a “general use” application with the requisite scientific data may be filed, for example, listing all lipsticks produced by a cosmetic manufacturer (Section 706(b)(2)(A)). It is only where a particular and different product is created with a new use—*e.g.*, “kiss proof” lipstick—involving a different combination of ingredients that a further listing application would have to be filed.

The \$250 fee for listing a diluent (21 C.F.R. 8.50(j)), is not required if the diluent is enumerated in the “general use” petition. Moreover, the Commissioner has prepared a list of certain diluents which will be listed without cost to the cosmetic industry. With regard to “batch certification”, the statute provides authority for exemptions (Section 706(3)) which are specifically carried over into the regulations (21 C.F.R. 8.17). Indeed, it is the present view of the Food and Drug Administration that there will be no requirement for certification of each new batch of listed color cosmetics. At most only periodic or spot-checking certification will be needed.

held permissible, the same reasoning would have to permit thirteen different suits in various district courts throughout the country. No one plaintiff would, of course, be bound by an adverse decision in any other case. The result would be precisely what Congress sought to avoid in enacting the judicial review provisions of the Food, Drug and Cosmetic Act (see our brief in *Abbott Laboratories*, No. 39, pp. 16-17, 21-22, 31-35)—that a single district judge could paralyze the nation-wide administration of the Act.*

III

THE FACTORY INSPECTION REGULATION IS PLAINLY NOT REVIEWABLE AT THIS JUNCTURE

The ruling of the court of appeals that the validity of the factory inspection regulation (21 C.F.R. 8.28 (a)(4), p. 35, *infra*) is not reviewable at the present juncture is, we submit, eminently correct. That regulation authorizes the Commissioner of Food and Drugs to suspend the pre-marketing certification service pro-

* We do not in these cases, as in *Abbott Laboratories*, No. 39, this Term, feel justified in asking this Court to consider the merits if it rejects our view on the ripeness aspect of the decision below. We believe, contrary to the view taken by the district judge (R. 75-76), that the issues of statutory construction can be resolved without evidentiary proceedings and that the record is now adequate to resolve them. But we recognize that the only issues which were certified by the district judge and the court of appeals for interlocutory appeal involved the denial of petitioners' motions to dismiss for want of justiciability and on grounds of sovereign immunity (R. 46-47, 117) and the denial of respondents' motion for summary judgment (R. 118). In these circumstances, we believe the appropriate relief, if the case is justiciable, is to remand for proceedings in the district court.

vided for in Section 706 where "free access" is denied Food and Drug employees to manufacturing facilities, and to processes and formulae relating to the production of color additives and their derivatives. The regulation speaks in permissive terms. The succeeding subsection, (b)(4), provides that, where a suspension notice is served, the party receiving the notice is entitled to a formal hearing as provided in 21 C.F.R. 130.14-130.26, on the "factual basis for the suspension." And it appears that if a "final order" granting suspension is issued by the administrative authority (see 21 C.F.R. 130.26), judicial review of that order is available (see 21 C.F.R. 130.31).

Against this background, there can be little doubt, we submit, that review of this regulation at this stage would be premature. There is nothing to indicate that the Commissioner intends to invoke the factory inspection provision in any particular case as to any party involved in this lawsuit. And even if there were a real probability of his intention to invoke it, this would still pose only a remote threat to a particular cosmetic manufacturer. The "threatened" party would be entitled to a hearing and judicial review before certification could be revoked.

Respondents' complaint fails to demonstrate how the existence of the regulation, *per se*, affects the conduct of its business or in any other way imposes an obligation to do or not to do anything. In these circumstances, we submit, the court below was plainly correct in concluding that "the possibility of unlawful injury to the plaintiffs is, on its face, too remote for declaratory relief" (R. 137).

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals with respect to the First, Second and Third Counts of the complaint should be reversed and its judgment with respect to the Fourth Count should be affirmed. The case should be remanded to the district court with instructions to grant the motion to dismiss the entire complaint for want of justiciability.

Respectfully submitted.

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APPENDIX

The Federal Declaratory Judgments Act, 28 U.S.C. § 2201, provides in pertinent part:

Creation of remedy

In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. * * *

Section 10 of the Administrative Procedure Act, 60 Stat. 243, 5 U.S.C. 1009, now recodified as 5 U.S.C. 701-704 (Public Law 89-554, 80 Stat. 378), provides in pertinent part:

- (a) This chapter applies, according to the provisions thereof, except to the extent that—
 - (1) statutes preclude judicial review, or
 - (2) agency action is committed to agency discretion by law.
- * * * * *

§ 702. RIGHT OF REVIEW

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.

§ 703. FORM AND VENUE OF PROCEEDING

The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action,

including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

§ 704. ACTIONS REVIEWABLE

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, or an appeal to superior agency authority.

The Federal Food, Drug and Cosmetic Act, as amended, provides, in pertinent part:

Section 201(t)(1), 21 U.S.C. 321(t)(1):

The term "color additive" means a material which—

- (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

- (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

Section 361, 21 U.S.C. 361, provides in pertinent part:

Adulterated cosmetics

A cosmetic shall be deemed to be adulterated—

(a) bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: ‘Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness’, and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this subsection and subsection (e) of this section the term ‘hair dye’ shall not include eyelash dyes or eyebrow dyes.

* * * * *

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).

Section 701, 21 U.S.C. 371, provides in pertinent part:

(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

* * * * *

(e) (1) Any action for the issuance, amendment or repeal of any regulation under section 401, 403(j), 404(a), 406 (a) or (b), 501(b), or 502 (d) or (h), 504 or 514 of this act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds the emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f)(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of Title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such addi-

tional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 346 and 347 of Title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.



Section 706, 21 U.S.C. § 376, provides in pertinent part:

(a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), 501(a)(4), or 601(e) of this Act, as the case may be, unless—

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c) of this section, for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) of this section with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) of this title if such article is a food, or within the meaning of section 601(a) of this Act if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a) of this Act).

(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities, which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the

regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s) of this Act.

(5)(A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.



(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) of this section and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided*, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

(d) The provisions of section 701 (e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection (b)(5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such nine-

tieth day) by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b)(5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409(f)(2); and

(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

(f) The Secretary shall by regulations (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

Section 704, 21 U.S.C. 374, provides:

(a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any

such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of this Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or

process drugs solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

***^(b)** Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or

packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food; a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

21 C.F.R. 8.1(f) provides in pertinent part:

A "color additive" is any material, not exempted under section 201(t) of the act * * *. This includes all diluents. * * * A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants, Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." * * *

21 C.F.R. 8.1(m) provides:

The term "diluent" means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

21 C.F.R. 8.1(u) provides:

The "hair dye" exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes

or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious substance in the "hair dye" is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.

21 C.F.R. 8.28(a)(4) provides:

(a) When it appears to the Commissioner that a person has:

* * * * *

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived; he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

21 C.F.R. 8.28(b) provides:

Upon receipt of the notice of suspension of service, the person so notified may request a hearing upon the factual basis for the suspension. The procedure at the hearing shall conform as nearly as possible to the procedure described in §§ 130.14-130.26 of this chapter.